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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,412	09/18/2003	Joseph Wang	37000-UT-0206	8931

5179 7590 03/29/2005

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,412	WANG ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/22/03; 8/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, drawn to a method of analyzing a sample, classified in class 436, subclass 425.

II. Claims 33-40, drawn to a microsphere comprising of an organic solvent soluble hydrophobic electroactive marker, classified in class 424, subclass 489.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as colorimetric particles or a solid phase incorporated with a fluorescence dye.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Stephen Slusher on March 2, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 1-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-40 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) introducing the microspheres incorporated a member of the specific binding pair; 2) introducing the sample containing the partner that forms a complex with the member of the specific binding pair incorporated therein; and 3) a correlating step of detecting the presence of the member of the specific binding pair.

Claim 10 is indefinite for reciting "wherein selecting comprises incubation" because it fails to recite what to be incubated.

Claim 20 lacks a correlation step of analyzing the sample for the presence of two or more analytes as recited in the preamble of the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10, 11, 15, 20, 24 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1, 2, 3, 7, 8, 73 and 74 of copending Application No. 10/796,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application '765 teaches a method of electrochemical detection of specific binding pair interaction, comprising the steps of: providing a first member of a first specific binding pair; associating the first member with a first electroactive nanoparticle; incubating the first specific binding pair associated with the first electroactive nanoparticle in a solution suspected to comprise the second member of the first specific binding pair; separating the first member forming a binding pair with the second member from the first member not forming a binding pair with the second member; and electrochemically detecting the first electroactive nanoparticle associated with the first member forming a specific binding pair with the second member; (claims 1, 10 –incubation, 15-nanoparticle); providing a first member of a second binding pair; associating the first member of the second binding pair with a second electroactive nanoparticle; incubating the first member of the second binding pair with a second electroactive nanoparticle; separation of unbound first member; electrochemically detecting the second electroactive nanoarticle associated with the first member of the second binding pair forming a specific binding pair with the second member; (equivalent to claims 20, 28-nanoparticle) wherein the specific binding pair complex is an antigen/antibody, enzyme/substrate, oligonucleotide/DNA; chelator/metal, enzyme/inhibitor, bacteria/receptor, virus/receptor; hormone/receptor, DNA/RNA, RNA/RNA, or oligonucleotide/RNA complex. (equivalent to claims 11 & 24).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8, 10-13, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Durst et al. (US 5,789,154).

Durst teaches a method comprising providing a liposome encapsulating an electroactive marker conjugated with an analyte; incubating the conjugated liposome with the sample containing the analyte and an absorbent substrate attached thereto a receptor that binds to the analyte to form a complex of receptor-analyte-liposome; lysing the liposome by adding a surfactant to release the electroactive marker; quantifying the electroactive marker corresponding to the amount of analyte in a sample by amperometric or potentiometric. Liposomes are prepared in aqueous solution containing the marker whereby the liposomes will include the marker in their interiors. The liposome sacs are prepared by vigorous agitation in the solution; followed by removal of uncapsulated electroactive marker. The conjugation of the analyte (first binding member) and the marker encapsulated liposome (microsphere) is prepared by procedures generally known in the art. Such techniques include covalent coupling, derivatization or activation, and the like. Derivatization includes using a functional group.

The analyte is an antibody, antigen, hapten; the receptor is any compound that recognizes a particular spatial and polar organization of a molecule, e.g. epitopic or determinant site. Illustrative receptor includes egg white avidin, streptavidin, antigen, antibody, Fab fragments, nucleic acids, protein A , protein G. Absorbent material (see abstract; col. 3, line 55- col. 4, line 11; col. 7, lines 25-28; col. 13, line 32-col. 14, line 5; col. 15, lines 12-17).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 10-13, 16-21, 24-26, 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Lu et al. (US 6,485,983).

Lu teaches a method for solid phase electrochemical, quantitative analysis of analytes contained in biological fluid samples. The method comprises providing liposome (polymeric microsphere) encapsulated therein an indicator/electroactive material (metal), such liposome is conjugated to a ligand; the ligand-bound labeled liposome is incubated with the sample containing analytes forming a specific binding pair complex, i.e. antigen/antibody; releasing the indicator/label by dissolving the liposome with a number of common lipid solvents (detergents) and detection is performed by anodic stripping voltammetry. The method can be used to perform a drug of abuse panel of assays on a given sample by simply utilizing a different labeled substance for each of the analytes of interest within a given sample. (see col. 4, line

50-col. 5, line 43; col. 7, line 60-col. 8, line 56; col. 9, line 10-col. 10, line 35). The liposome is incubated with the indicator in an organic solvent (see example 1).

Claims 1-4, 6-11, 14, 15, 17, 20-24, 27, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Bamdad (US 2003/0059955).

Bamdad teaches a method of detection of the presence of a member of a specific binding pair, the method comprising: providing semiconductor nanocrystal (nanoparticle or redox-active molecules such as ferrocene derivatives (metallocene)) embedded within or attached to a microparticle such as a colloidal particle. Colloidal particles include self-suspendable/insoluble particles including organic, polymeric, and metal particles. The polymeric particle/microsphere can be polystyrene. (see [0034]; selecting for the microsphere by formation of a specific binding pair complex and electrochemically testing for the electroactive marker/nanocrystal. The first member of a specific binding pair is attached to the microsphere/particle through covalent bond and a functional group. The first member of a specific binding pair is attached to the microsphere and a second member of the specific binding pair attaches to a substrate such as a magnetic bead. Binding partners can be two different types of antibodies, proteins, enzyme/substrate, antibody/antigen, antibody/hapten, carrier protein/substrate, receptor/hormone, etc. (see ([0048]; [0031]; [0034]; [0058]; [0063]; [0074] lines 1-13; [0073]). Regarding claim 20, Bamdad teaches providing a second nanoparticle different from the first nanoparticle, attaching the second binding pair member specific to the second analyte to the second microsphere/nanoparticle; incubating the first microsphere and the second microsphere in a solution comprising the sample; selecting the first and

second microspheres by formation of specific binding pair complexes; and electrochemically testing the first electroactive marker and the second electroactive marker.([0013], [0073]; example 4 [0080], [0081]).

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 7, 10-12, 17, 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Knoll (US 6,548,311).

Knoll teaches a sandwich assay format comprising a microelectrode on which capture antibodies that bind to the analytes are immobilized; antigens (analyte) and marker particles charged with an electroactive material and conjugated with an antibody that binds to the analyte are added to the electrode to form complex of electrode-capture antibody-analyte-antibody-marker particles (Electroactive material); electrochemically testing for the electroactive marker by measuring the voltage. The particles are microspheres of SiO2, latex, diamagnetic, paramagnetic and other materials having diameters between 15 nm and 25 nm. The electroactive material may emerge from the particle from the particle surface by diffusion. The binding pair complex

is antigen/antibody; enzyme/substrate; DNA/RNA (fig. 20 (e) and col. 13, line 65-col. 14, line 41; fig. 17).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 13, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
3/18/05